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10/650,217

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John Graeme Houston

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EXAMINER

AUGHENBAUGH, WALTER

ART UNIT

PAPER NUMBER

1794

NOTIFICATION DATE

DELIVERY MODE

04/07/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docketing@bgllp.com

|                              |  |                                       |  |
|------------------------------|--|---------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/650,217     | <b>Applicant(s)</b><br>HOUSTON ET AL. |  |
|                              | <b>Examiner</b><br>WALTER B. AUGHENBAUGH | <b>Art Unit</b><br>1794               |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 33-37, 47-49 and 54 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 33-37, 47-49 and 54 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application           |
| Paper No(s)/Mail Date _____  | 6) <input checked="" type="checkbox"/> Other: <u>See Continuation Sheet</u> |

Continuation of Attachment(s) 6). Other: copy of foreign priority document.

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 22, 2009 has been entered.

### ***Acknowledgement of Applicant's Amendments***

2. Applicant's amendments in claims 33-35 and 37 in the Amendment filed January 22, 2009 have been received and considered by Examiner.

3. Claim 49 is incorrectly labeled "(Currently Amended)" in the Amendment filed January 22, 2009. Claim 49 is identical to claim 49 in the previous claim set, so it should be labeled "(Previously Presented)".

## **WITHDRAWN REJECTION**

4. The 35 U.S.C. 102 rejection of claims 33-37, 47-49 and 54 made of record in the previous Office Action mailed July 23, 2008 has been withdrawn due to Applicant's argument in the Amendment filed January 22, 2009. The Office has obtained a copy of the foreign priority document, and a copy is included with this Office Action.

## **NEW OBJECTIONS**

### ***Specification***

5. The disclosure is objected to because of the following informalities: in regard to the amendments in the specification dated August 19, 2003:

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Page 10, third paragraph: both references characters 87 and 89 are struck through (line 6 of paragraph). This should be corrected.

Page 11, third paragraph: both references characters 16 and 14 are struck through (line 1 of paragraph). This should be corrected.

Appropriate correction is required.

### ***NEW REJECTIONS***

#### ***Double Patenting***

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 33-37, 47-49 and 54 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over each of independent claims 1 and 4 (and dependent claim 10) of U.S. Patent No. 7,185,677. Although the conflicting claims are not identical, they are not patentably distinct from each other because Applicant’s invention claimed in claims 33 and 47 corresponds to that which is claimed in each of claims 1, 4 and 10 of U.S. Patent No.

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7,185,677. The “elongate member... defining at least a portion of a helix” of claim 1 of US ‘677 and the “helical formation comprising an elongate member defining at least a portion of a helix” of claim 4 of US ‘677 corresponds to the “internal helical formation” of instant claim 33 and to the “at least one vane stationarily attached to an interior [mesh member of the stent]” of instant claim 47. Fig. 1 shows that a mesh stent is a suitable article as the conduit claimed in claims 1 and 4, and furthermore, one of ordinary skill in the art would have recognized that the mesh-type of stent is a common/typical type of stent that is well known to one of ordinary skill in the art. Also note that claim 10 recites that the helical formation is used in a stent.

In further regard to claim 47, the structure of the “elongate member” and “helical formation” claimed in US ‘677 appears to fall within the scope of Applicant’s terminology “vane”, “vane member” and “vane means” used in the following paragraphs of the instant specification:

The helical flow inducing means may comprise a bio-compatible insert, which may comprise helical vane means, which may, for example, be fashioned like fan or propeller blades or which might be elongated spiral projections from the inner surface of a cylindrical insert. Paragraph 0014.

The mesh material may comprise segments extending helically around the periphery of the stent and the internal spiral formation comprise vane members attached to such segments--in other words, the design parameters for the stent may include both internal and external modification. Paragraph 0022.

Attached to some of the segments 102, on the inside of the stent 101, are vane members 104. In a welded wire construction, these could be plates welded to segments, while in an expanded sheet construction, the vane members 104 could be parts of the sheet, leaving corresponding holes in the mesh. Paragraph 0053 and Figures 9-12.

Furthermore, in regard to the claimed helix angle range, while the helix angle of the insert shown in Fig. 1 of US ‘677 appears to fall within the range of 5 to 16 degrees relative to the longitudinal axis of the mesh member, in the instance where Applicant convincing shows that

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the helix angle of the insert shown in Fig. 1 of US '677 does not fall within the claimed range, claim 4 of US '677 recites that the structure of the insert is such that it imparts a spiral flow pattern onto fluid flowing through the conduit (lines 18-19 of claim 4). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have varied the helix angle of the insert of US '677 in order to achieve the desired degree of spiral flow depending on the particular desired end result, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art in the absence of unexpected results. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). MPEP 2144.05 II.B.

8. Claims 33-37, 47-49 and 54 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over each of independent claims 1 and 7 of U.S. Patent No. 7,331,989. Although the conflicting claims are not identical, they are not patentably distinct from each other because Applicant's invention claimed in claims 33 and 47 corresponds to that which is claimed in each of claims 1 and 7 of U.S. Patent No. 7,331,989. The "insert comprising a longitudinally extending member defining a partial helix..." of claim 1 of US '989 and the "insert comprising a longitudinally extending member forming a partial helix..." of claim 7 of US '989 corresponds to the "internal helical formation" of instant claim 33 and to the "at least one vane stationarily attached to an interior [mesh member of the stent]" of instant claim 47. Fig. 1 shows that a mesh stent is a suitable article as the conduit claimed in claims 1 and 7, and furthermore, one of ordinary skill in the art would have recognized that the mesh-type of stent is a common/typical type of stent that is well known to one of ordinary skill in the art.

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In further regard to claim 47, the structure of the insert claimed in US '989 appears to fall within the scope of Applicant's terminology "vane", "vane member" and "vane means" used in the following paragraphs of the instant specification:

The helical flow inducing means may comprise a bio-compatible insert, which may comprise helical vane means, which may, for example, be fashioned like fan or propeller blades or which might be elongated spiral projections from the inner surface of a cylindrical insert. Paragraph 0014.

The mesh material may comprise segments extending helically around the periphery of the stent and the internal spiral formation comprise vane members attached to such segments--in other words, the design parameters for the stent may include both internal and external modification. Paragraph 0022.

Attached to some of the segments 102, on the inside of the stent 101, are vane members 104. In a welded wire construction, these could be plates welded to segments, while in an expanded sheet construction, the vane members 104 could be parts of the sheet, leaving corresponding holes in the mesh. Paragraph 0053 and Figures 9-12.

Furthermore, in regard to the claimed helix angle range, while the helix angle of the insert shown in Fig. 1 of US '989 appears to fall within the range of 5 to 16 degrees relative to the longitudinal axis of the mesh member, in the instance where Applicant convincing shows that the helix angle of the insert shown in Fig. 1 of US '989 does not fall within the claimed range, US '989 discloses that the purpose of the helical insert is to effect helical flow in the conduit (see, for example, abstract). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have varied the helix angle of the insert of US '989 in order to achieve the desired degree of helical (spiral) flow depending on the particular desired end result, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art in the absence of unexpected results. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). MPEP 2144.05 II.B.



***Claim Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 33, 34 and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Trescony et al. (USPN 5,653,745).

In regard to claims 33 and 34, Trescony et al. teaches a tubular mesh member having an internal helical formation (which would induce spiral-flow therethrough) (col. 2, lines 6-10 and col. 4, lines 18-23 and Fig. 5). Each of the valleys of the undulating inner wall of the tubular member correspond to the claimed internal helical formation. Fig. 5. The tubular member of Trescony et al. is a tubular mesh member in the instance where the material of the tubular member is a knitted or woven fabric (col. 2, lines 6-10 and col. 4, lines 18-23). The helical angle of the twisted tubular member shown in Fig. 5 falls within the range of 5-16 degrees relative to the longitudinal axis of the tube. The tubular mesh member of Trescony et al. corresponds to the structure of a stent (as claimed in both claims 33 and 34) because it is a tubular mesh member (stents are tubular mesh members).

In regard to claim 36, the helix angle of the internal helical formation is adjustable because Trescony et al. teach that the pleats of the tubular member are twisted along the axis of the graft to provide improved kink resistance (col. 2, lines 39-42).

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***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. Claims 33 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trescony et al. (USPN 5,653,745).

Trescony et al. teach the tubular mesh member as discussed above in regard to claim 33.

In regard to claim 33, in the instance where Applicant convincingly shows that the helix angle of Trescony et al. is outside of the claimed range of 5 to 16 degrees, Trescony et al. teach that the pleats of the tubular member are twisted along the axis of the graft to provide improved kink resistance (col. 2, lines 39-42 and col. 4, lines 34-41). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have varied the helix angle of the pleats of Trescony et al. in order to achieve the desired degree of kink resistance depending on the particular desired end result, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art in the

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absence of unexpected results. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). MPEP 2144.05 II.B.

In regard to claim 54, Trescony et al. fails to explicitly teach that the helix angle is about 16 degrees as claimed. However, Trescony et al. teach that the pleats of the tubular member are twisted along the axis of the graft to provide improved kink resistance (col. 2, lines 39-42 and col. 4, lines 34-41). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have varied the helix angle of the pleats of Trescony et al. in order to achieve the desired degree of kink resistance depending on the particular desired end result, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art in the absence of unexpected results. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). MPEP 2144.05 II.B.

### ***Response to Arguments***

13. Applicant's arguments presented in the Amendment filed January 22, 2009 in regard to the 35 U.S.C. 102 rejection are moot due to the withdrawal of this rejection in this Office Action due to Applicant's argument in the Amendment filed January 22, 2009. The Office has obtained a copy of the foreign priority document, and a copy is included with this Office Action.

### ***Conclusion***

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Walter B. Aughenbaugh whose telephone number is (571) 272-1488. While the examiner sets his work schedule under the Increased Flexitime Policy, he can normally be reached on Monday-Friday from 8:45am to 5:15pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rena Dye, can be reached on (571) 272-3186. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Walter B Aughenbaugh /  
Examiner, Art Unit 1794

03/29/09